FILED UNDER SEAL PURSUANT TO PROTECTIVE ORDER

IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

SEAGEN INC.,

Plaintiff,

v.

DAIICHI SANKYO CO., LTD.,

Defendant,

ASTRAZENECA PHARMACEUTICALS LP, and ASTRAZENECA UK LTD,

Intervenor-Defendants.

Civil Action No. 2:20-CV-00337-JRG

FILED UNDER SEAL

SEAGEN'S OPPOSITION TO DSC'S MOTION FOR SUMMARY JUDGMENT

TABLE OF CONTENTS

PAGE

TABLE OF CONTENTS
(CONTINUED)

PAGE

TABLE OF AUTHORITIES

PAGE(S)

Cases

TABLE OF AUTHORITIES
(CONTINUED)

PAGE(S)

TABLE OF AUTHORITIES
(CONTINUED)

PAGE(S)

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Pursuant to the First Amended Docket Control Order (Dkt. 229), Seagen hereby responds to DSC's Motion for Summary Judgment.

I. INTRODUCTION

Despite Defendants' best attempt to paint written description in this case as an issue on which no facts are in dispute, it is clear that the parties' experts starkly dispute how one of ordinary skill in the art would have evaluated the patent and its priority applications and the sufficiency of the priority applications' disclosure. Seeking to elide that dispute, Defendants ignore a critical aspect of the claims: the recitation of a precise formula depicting the structure of the claimed compounds. Defendants also dismiss the exemplary tetrapeptides disclosed in the specification, and argue that they do not "point toward the claimed subgenus."

But as set forth in detail in her detailed report, Seagen's expert, Dr. Bertozzi, opines that the priority applications disclose formulas that match the claimed structure, and that they specifically identify a tetrapeptide as one option for the linker. The amino acids called for in the claims are also disclosed in the applications. Defendants' expert offers a different view, but this does not suffice to show that summary judgment is appropriate. Defendants' argument regarding "blaze marks" also ignores a clear dispute in the expert evidence as to whether the priority applications are sufficient. Seagen's expert properly took into account what was known in the art, as a central tenet of written description jurisprudence is that the disclosure is to be read from the perspective of a skilled artisan who is deemed to have knowledge of the prior art.

Defendants' other arguments are also unpersuasive. Defendants devote pages to recount testimony from Seagen's inventors, who according to Defendants testified that they did not have possession of the invention because they had not actually reduced it to practice. But actual reduction to practice is not the relevant inquiry here, and Defendants' reliance on the inventors'

testimony is misplaced. Nor is the inventors' alleged inability to identify "blaze marks" in the priority applications dispositive here, and Defendants mischaracterize the inventors' testimony in any event. Defendants' made-up legal standard requiring that the blaze marks point to the exact claimed subgenus is also contrary to precedent and should be rejected.

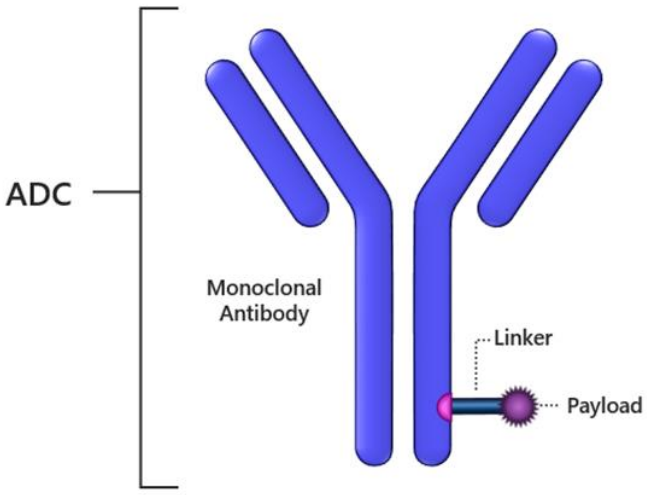
II. STATEMENT OF ISSUES TO BE DECIDED BY THE COURT

Whether genuine factual disputes exist regarding whether the priority applications filed before the Ogitani reference provide adequate written description support for the asserted claims, such that summary judgment on the basis of anticipation is not appropriate.

III. BACKGROUND

A. Antibody-Drug Conjugates (ADCs)

Antibody-drug conjugates, or "ADCs," are drugs that combine a highly potent chemotherapeutic agent with a tumor-selective antibody by way of a linker unit. (Declaration of Carolyn Bertozzi, Ph.D. ("Bertozzi Decl.") (attaching Bertozzi Decl. Ex. A, Rebuttal Expert Report of Carolyn Bertozzi ("Bertozzi") at ¶ 38).) As shown below, an ADC has three basic components: an antibody, a toxic drug (or "payload"), and a "linker" between them that attaches the two. (*Id.*)



ADCs target cancer cells using the antibody component, and then deliver a drug payload directly to the cancer cell. (*Id.* ¶ 39.) Unlike chemotherapy, where drugs are administered in an untargeted fashion, the toxic drug in an ADC gets delivered where it is needed. (*Id.*) This allows the use of more powerful chemotherapeutic drugs with fewer of the side effects and systemic toxicities than those drugs would otherwise cause to the body. (*Id.*)

B. History of Seagen's ADC Technology

In the late 1980s and 1990s, Bristol-Myers-Squibb ("BMS") conducted research into antibody-directed therapeutics, including antibody-drug conjugates. (Bertozzi ¶ 42.) BMS initially focused its ADC research on developing *acid-cleavable* linkers—linkers designed with the goal of maintaining stability in the neutral pH environment of the circulatory system but that degrade in the low-pH tumor microenvironment, resulting in the release of the drug payload unit. (*Id.*; Opp. Ex. 1, SGIEDTX00362049.) The linkers were used to attach doxorubicin, an anti-cancer drug. (Bertozzi ¶ 42.)

BMS later expanded its focus to include development of *protease-cleavable* linkers, that is, linkers that are capable of being cut by enzymes within the target cell called "proteases." (Bertozzi ¶ 43; Opp. Ex. 2, SGIEDTX00085997 ("Dubowchik Apr. 2002").) In the 1990s, a particular protease, cathepsin B, was thought to be primarily responsible for this cleavage, because it is often highly expressed in tumors. (Bertozzi ¶ 43; Opp. Ex. 3, DSC_ENHERTU_00391635 at -635.) This work was spun out from BMS into the newly formed Seagen in the late 1990s. (Bertozzi ¶ 43.) The '039 patent builds on this technology.

Seagen's ADC technology is the result of years of research and development by Seagen scientists. (*Id.* ¶ 44.) At its inception, Seagen exclusively licensed BMS's ADC technology, including its protease-cleavable linker systems. (*Id.*) Dr. Peter Senter, formerly of BMS, also joined Seagen, and has been the head of chemistry at Seagen since he joined the company. (*Id.*)

At Dr. Senter's direction, protease-cleavable linkers became a core focus of Seagen's ADC technology. (*Id.*) Seagen is now widely recognized as a pioneer in the development of protease-cleavable ADC linker systems. (*Id.*)

Seagen's research into protease-cleavable linkers was incorporated into Seagen's contemporaneous patent filings. It was also published in the scientific literature in 2003 by Dr. Doronina, one of the named inventors, and colleagues. (Bertozzi ¶ 47; Opp. Ex. 4, SGIEDTX00088427.) Her publication demonstrated the superiority of Seagen's ADC technology compared to other technologies. (*Id.*) As explained by Dr. Senter, this technology allowed Seagen to create ADCs that "were more stable, led to specific cell killing activity and regression of tumor in preclinical animal models, and displayed therapeutic indices as high as 60 times compared to less stable acid-cleavable linkers." (Bertozzi ¶ 47; Declaration of Peter Senter ("Senter Decl.") (attaching Senter Decl. Ex. A, Witness Statement of Peter Senter at ¶ 13).)

The co-inventors' work at Seagen with peptide libraries also expanded the list of amino acids for designing ADCs that would be intracellularly cleaved. Prior to 2003, cathepsin B was thought to be the primary protease responsible for intracellular cleavage. (*See, e.g.*, Opp. Ex. 2, SGIEDTX00085997 at -997; Opp. Ex. 3, DSC_ENHERTU_00391635 at -635; *see also* Bertozzi ¶¶ 68-69.) On this basis, the art discounted certain amino acid sequences, including tetrapeptides, for use in ADCs as they "were considered to have significant potential liabilities" due to slow drug release. (*Id.*) Nevertheless, after testing many different amino acid sequences, including di-, tri-, and tetrapeptides, the co-inventors discovered that they all cleaved intracellularly - even sequences that were not substrates for cathepsin B. (*See, e.g.*, Opp. Ex. 5, [redacted] *see also* Bertozzi ¶¶ 70-79.) Their invention, as described in the priority applications, taught that a vast array of amino acid sequences could be

used in protease-cleavable linker design. (Opp. Ex. 6, Kline Tr. [redacted]; Opp. Ex. 7, Doronina Tr. at [redacted] Opp. Ex. 20, Senter Tr. [redacted] Opp. Ex. 8, Toki Tr. [redacted].)

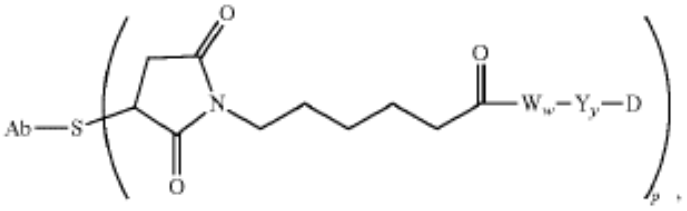
Seagen's linker technology has been used to develop several FDA-approved ADCs for treating Hodgkin's lymphoma and other CD30-positive lymphomas, B-cell lymphoma, advanced or metastatic urothelial cancer, and multiple myeloma, among other conditions. (Bertozzi ¶ 48.) Seagen received FDA approval for its first ADC, SGN-35 (now marketed as Adcetris®) in 2011. (*Id.*) Adcetris was the second ADC ever to receive approval, and the first approved ADC to employ a protease-cleavable linker. (*Id.*)

Of the eleven ADCs currently approved by the FDA, at least five employ protease cleavable linkers. (Bertozzi ¶ 49.) Four of these are marketed by Seagen or its current collaborators. Of the remaining, one follows from a past collaboration between Seagen and DSC: DS-8201 (marketed as Enhertu®), the drug that is the subject of this litigation. (*Id.*)

C. The '039 Patent

The '039 patent issued on October 20, 2020 from U.S. Patent Application No. 16/507,839 (the "'839 application"), which was filed on July 10, 2019. (Opp. Ex. 9, SGIEDTX00003953 at -953 ("'039 Pat."), front page.) The '839 application is the last application filed in a series of seven divisional and continuation applications with the same specification filed between November 5, 2004, and July 10, 2019, starting with U.S. Patent Application No. 10/983,340 (Opp. Ex. 10, SGIEDTX00002840 at -840 ("'340 application").) (*Id.*; Bertozzi ¶ 292.) The '039 patent claims priority to four provisional applications, with the earliest filed on November 6, 2003. (*Id.*) The named inventors on the '039 patent are Svetlana Doronina, Peter Senter, Brian Toki, and Toni Beth Kline. (*Id.*; Bertozzi ¶ 51.)

The '039 patent discloses ADC technology that enables the delivery of chemotherapeutic drugs directly to cancer cells by linking them to antibodies. (Bertozzi ¶¶ 52-53.) The claims of the '039 patent are directed to ADCs that comprise a protease cleavable linker, and cover ADCs with linkers having a specific formula, shown below. (*Id.*)



In the formula, Ab is an antibody, S is a sulfur atom on a cysteine residue of the antibody, W_w is an amino acid unit, Y is a spacer unit, D is a drug moiety, y is 0, 1, or 2, and p ranges from 1 to about 20. ('039 Pat. at Claim 1; Bertozzi ¶¶ 53-58.)

The amino acid unit W_w is protease-cleavable. (Bertozzi ¶ 55.) In the claims, it is a tetrapeptide, meaning the unit has four amino acids. (*Id.*) Each amino acid has the structure shown above in which R^{19} is a hydrogen or benzyl group. (*Id.*) The amino acid glycine (abbreviated "G" or "Gly") has hydrogen as the R^{19} group and the amino acid phenylalanine (abbreviated "F" or "Phe") has benzyl as the R^{19} group in this formula. (*Id.*) Thus, the W_w unit in claim 1 is directed to a tetrapeptide in which each amino acid is glycine or phenylalanine. (*Id.*)

IV. LEGAL STANDARDS

A. Summary Judgment

"Because of the presumption of validity that attaches to an issued patent, invalidity for lack of written description must be proven by clear and convincing evidence." *GeoTag, Inc. v. Frontier Commc'ns Corp.*, No. 2:10-CV-00265-JRG, 2014 WL 129835, at *3 (E.D. Tex. Jan. 14,

2014) (Gilstrap, J.). "[C]ompliance with the written description is a question of fact on which summary judgment is appropriate only in narrow circumstances." *Steuben Foods, Inc. v. Oystar USA, Inc.*, 405 F. Supp. 3d 452, 464 (W.D.N.Y. 2019). There are only "rare instances in which the facts firmly establish that a party has met or failed to meet the written-description requirement." *Abbott Biotechnology Ltd. v. Centocor Ortho Biotech, Inc.*, 35 F. Supp. 3d 163, 178 (D. Mass. 2014). "Summary judgment on the written description requirement is not appropriate if there is conflicting evidence as to what one of ordinary skill in the art would have known." *Kowalski v. Mommy Gina Tuna Res*., 574 F. Supp. 2d 1165, 1167 (D. Haw. 2008) (citations omitted).

B. Written Description

The written description requirement provides that a patent's disclosure should allow persons of ordinary skill in the art "to recognize that [the inventor] invented what is claimed." *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (2010) (citation omitted). For genus claims, this standard may be met either by describing "a representative number of species falling within the scope of the genus," or "structural features common to the members of the genus so that one of skill in the art can 'visualize or recognize' the members of the genus." *Id.* at 1350. "Because the specification is viewed from the perspective of one of skill, in some circumstances, a patentee may rely on information that is 'well-known in the art' for purposes of meeting the written description requirement." *Boston Sci. Corp. v. Johnson & Johnson*, 647 F.3d 1353, 1366 (Fed. Cir. 2011).

"Yet whatever the specific articulation, the test requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art. Based on that inquiry, the specification must describe an invention understandable to that skilled artisan and show that the inventor actually invented the invention claimed." *Ariad*, 598 F.3d at 1351.

No rigid requirement exists that the disclosure contain either examples or an actual reduction to practice. *Allergan, Inc. v. Sandoz Inc.*, 796 F.3d 1293, 1308 (Fed. Cir. 2015). For generic claims, a number of factors are considered for evaluating the adequacy of the disclosure, including "the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, [and] the predictability of the aspect at issue." *Ariad*, 598 F.3d at 1363 (citations omitted).

A genus can be adequately described by "a precise definition, such as by structure, formula, chemical name, physical properties, or other properties, of species falling within the genus sufficient to distinguish the genus from other materials." *Ariad*, 598 F.3d at 1350; *see also Capon v. Eshhar*, 418 F.3d 1349, 1356 (Fed. Cir. 2005) (rejecting requirement of "complete nucleotide sequence of 'at least one' chimeric gene" as not grounded in precedent). This formulation is especially apposite in the context of a chemical invention such as that claimed in the '039 patent, where the claim recites a formula and the specification provides a defined set of substituents from which claimed substituents are selected. *Novartis Pharms. Corp. v. Plexxikon Inc.*, No. PGR2018-00069, Paper 16 at 15-17 (P.T.A.B. Jan. 16, 2019); *In re Driscoll*, 562 F.2d 1245, 1249-50 (C.C.P.A. 1977).

V. ARGUMENT

Defendants' motion presents a single issue: have defendants shown that there are no genuine issues of material fact as to whether the '039 patent's claim to priority to applications filed before the Ogitani reference is supported by the written description in those applications? If the patent can claim the benefit of a priority application, the '039 patent claims are not anticipated. Defendants argue that it is beyond genuine dispute that the priority applications lack written description support for the tetrapeptide limitation of the claims, such that the '039 patent

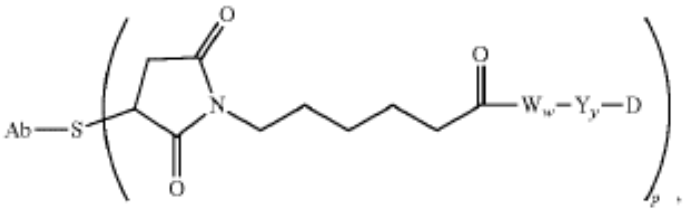
claims are not entitled to a filing date earlier than July 10, 2019. Defendants' arguments fail.

A. There Are Genuine Issues of Material Fact in Dispute Regarding Whether the Disclosure of the Priority Applications Meets the Written Description Requirement

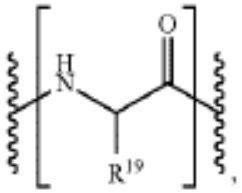
Defendants argue that because the priority applications allegedly present a "laundry list" of amino acids resulting in millions of potential compounds, they lack written description support for the claims. (Mot. at 16-20.) While the textual disclosure of the priority applications is not in dispute, whether that disclosure – which provides a specific formula, plus a list of options from which to select the substituents, with examples that further narrow those choices – is sufficient is indeed in dispute, as set forth in detail in Dr. Bertozzi's reasoned report. (Bertozzi ¶¶ 295-305, 172-182.) "A disagreement between qualified experts is not grounds for summary judgment." *Allure Energy, Inc. v. Nest Labs, Inc.*, No. 9-13-CV-102, 2015 WL 11110607, at *2 (E.D. Tex. May 11, 2015). Defendants therefore cannot meet their burden to show that the priority applications fail to meet the written description requirement.

1. The Priority Applications Disclose a Precise Chemical Formula and Narrow the Options from Which the Substituents Could Be Selected

Defendants' motion ignores a crucial aspect of the claims: the recitation of a precise formula depicting the structure of the claimed compound. Claim 1 recites an ADC having a linker unit defined by a formula "-A_a-W_w-Y_y-", which consists of the specific chemical structure for maleimidocaproyl (A_a), a tetrapeptide amino acid unit (W_w) consisting of either glycine or phenylalanine peptides, and a Spacer unit (Y_y). ('039 Pat. at Claim 1; Bertozzi ¶¶ 63, 85, 295.) This linker is capable of linking, on the one end, to the antibody (Ab) via a sulfur atom (S) on a cysteine residue of the antibody, and on the other end, to a drug moiety (D). (*Id.*)

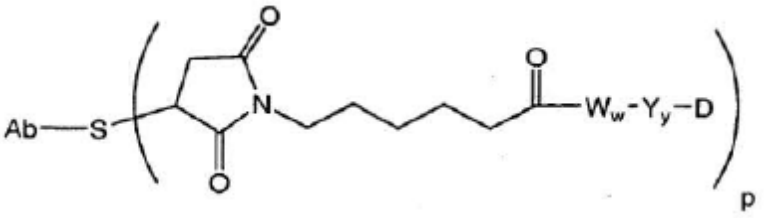


The claim further defines each of the amino acids W in the tetrapeptide amino acid unit as having the structure below, wherein R^{19} is a side chain that can be either a hydrogen (resulting in the amino acid glycine, depicted as gly or G) or benzyl (resulting in the amino acid phenylalanine, depicted as phe or F). (Bertozzi ¶ 295; '039 Pat. at Claim 1.)

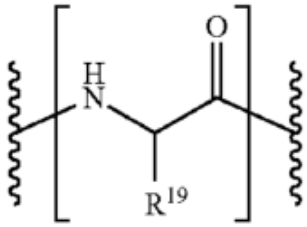


Thus, the claims of the '039 patent provide a specific chemical formula for the linker, including each of the components of this linker, which serves to link an antibody (Ab) to a drug moiety (D). (*Id.*) And they further define the substituents for the tetrapeptide amino acid unit by a specific formula having a particular structure. (*Id.*)

The priority applications disclose this precise formula, and also define the substituents, including those that form the tetrapeptide amino acid unit. For example, the '340 application (which was filed on November 5, 2004) provides the same formula recited in Claim 1:



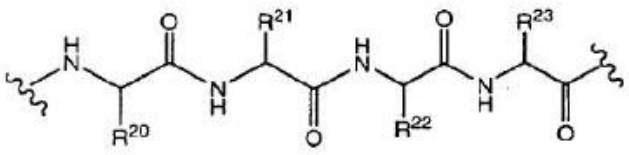
(Bertozzi ¶ 62; *Compare* '340 application ¶ 0715 to '039 Pat. at 331:37–45.) The '340 application also provides a structure for each amino acid within the peptide unit, which is exactly the same structure recited in claim 1:



(Bertozzi ¶¶ 64, 296; '340 application ¶ 0684.)

The '340 application discloses detailed information about the amino acid unit. (Bertozzi ¶ 64.) In particular, it discloses that the amino acid unit "is a dipeptide, tripeptide, *tetrapeptide*, pentapeptide . . . or dodecapeptide unit," and further states that in one embodiment, the amino acid unit "is a dipeptide, tripeptide, *tetrapeptide* or pentapeptide." (Bertozzi ¶¶ 64, 296; '340 application ¶¶ 0684, 0694) (emphasis added).) The application states that each R^{19} side chain is selected from a group of 39 side chains, including hydrogen and benzyl (corresponding to glycine and phenylalanine, respectively), which are the side chains claimed in claim 1 of the '039 patent. (Bertozzi ¶¶ 65, 296; '340 application ¶ 0685.) Thus the '340 application includes within its written description a tetrapeptide that consists of amino acids with R^{19} groups of either hydrogen (gly) or phenylalanine (phe). (Bertozzi ¶ 297.)

The '340 application also provides illustrative examples of tetrapeptides, which were well-known in the art. (*See, e.g.*, Opp. Ex. 10, SGIEDTX00002840 at -899; Opp. Ex. 11, SGIEDTX00362535; Opp. Ex. 12, SGIEDTX00362513; Opp. Ex. 13, SGIEDTX00362444; *see also* Bertozzi ¶ 298.) The disclosed tetrapeptides are depicted by the following formula:



(IX)

wherein R^{20}, R^{21}, R^{22} and R^{23} are as follows:

R^{20}	R^{21}	R^{22}	R^{23}
H	benzyl	isobutyl	H; and
methyl	isobutyl	methyl	isobutyl.

(Bertozzi ¶ 298.) The formula provides a total of four types of amino acids for use in the tetrapetides: glycine (H), phenylalanine (benzyl), leucine (isobutyl), and alanine (methyl). (*Id.*) The formula then depicts two tetrapeptides, made up of two sets of these four amino acids. The first exemplary tetrapeptide consists of three types of amino acids: glycine, phenylalanine, and leucine. The second exemplary tetrapeptide consists of just two types of amino acids: alanine and leucine. (*Id.*)

Defendants argue that the priority applications' disclosure results in "nearly 48 million linkers in the tetrapeptide category alone," a disclosure that they argue is too broad to support the subgenus of gly/phe tetrapeptides. (Mot. at 20.) Yet Defendants admit that the scope of the claims is limited to only "a minute subgenus" of those linkers: only 81 tetrapeptides, not millions. (Mot. at 16; *see also* Opp. Ex. 14, Lambert Tr. 81:7-15, 94:10-95:14 (admitting that by the 2000s, synthesizing tetrapeptide sequences was "well known and fairly straightforward" and making 81 tetrapeptide sequences "would be doable.").) Defendants also dismiss the exemplary tetrapeptides disclosed in the specification, and argue that they do not "point toward the claimed subgenus." (*Id.*)

The expert evidence on this issue is disputed, however. As Seagen's expert Dr. Bertozzi explains in her detailed report, a person of ordinary skill in the art would not have considered all of the millions of potential tetrapeptides. Rather, as discussed in more detail in Section V.B.

below, the exemplary tetrapeptides would have narrowed the skilled artisan's choices to two amino acids and their respective isomers: glycine or phenylalanine (with the understanding that phenylalanine has two stereoisomers). (Bertozzi ¶¶ 295-305, 172-182.) Given the far smaller set of amino acids used in the examples, a person of ordinary skill would have understood that the claimed ADCs included those using tetrapeptide units with gly/phe amino acids. (*Id.*)

2. The Applicable Law Does Not Dictate the Result Urged By Defendants

As discussed above, the '039 patent claims recite a precise formula, with the priority applications providing the substituents, including those that form the tetrapeptide amino acid unit. The case law provides a framework for analyzing the sufficiency of disclosure for chemical inventions in which the claims recite a precise formula having a defined structure, with substituents selected from a list of options provided in the specification. *Novartis*, No. PGR2018-00069, Paper 16 at 14-17; *Driscoll*, 562 F.2d at 1249-50.

In *Novartis*, the specification disclosed a general formula including the side chain R^1, listing 23 options from which R^1 could be selected, including "optionally substituted lower alkyl" and "optionally substituted heteroaryl." *Novartis*, No. PGR2018-00069, Paper 16 at 3-4. The claim recited the same formula, but specified "optionally substituted lower alkyl" and "optionally substituted heteroaryl," for the side chain R^1, that is, two of the 23 options explicitly disclosed in the specification. *Id*. at 4. The petitioner argued that there were no "blaze marks" in the specification pointing a person of ordinary skill in the art toward the two choices for R^1 recited in the claim, instead providing lists of options that "encompass[] an enormous number of possible R^1 groups." *Id.* at 10-11. The Board rejected the petitioner's argument, because the "recited R^1 was selected from a Markush group of 23 substituents disclosed for R^1" in the formula provided in the specification. *Id.* at 16-17.

Similarly in *Driscoll*, the specification disclosed a general formula that provided fourteen options for the side chain R, including "alkylsulfonyl (C1-C6)." *Driscoll*, 562 F.2d at 1247. The claim recited the same formula, but specified "alkylsulfonyl (C 1-C 6)" for the side chain R, that is, one of the 14 options explicitly disclosed in the specification. *Id*. at 1246. The CCPA pointed out that the only difference between the claims and the specification was "the definition of the substituent designated by R," wherein "R corresponds to a Markush group of fourteen variable substituents (the R group), one of which is alkylsulfonyl (C 1-C 6)." *Id.* at 1249. Rejecting the applicability of *In re Ruschig*, the CCPA held that "we must view the disclosure of the earlier filed application as would a person skilled in the art and determine whether it reasonably conveys the information that as of the filing date thereof appellant had possession of" the claimed class of compounds. *Id.* at 1249-50.

The same analysis applies here. As discussed above, the priority applications (1) explicitly disclose that the amino acid unit can be a tetrapeptide, (2) disclose the same formula for both the overall compound and the amino acid unit recited in the claim, (3) disclose a list of 39 side chains for R^{19} in the amino acid unit that includes the two side chains recited in the claims, and (4) provide examples of tetrapeptides that would have narrowed the choices to two amino acids and their respective isomers: glycine or phenylalanine. (Bertozzi ¶¶ 295-305, 172-182.) As in *Novartis* and *Driscoll*, the R^{19} recited in claim 1 of the '039 patent is selected from a Markush group of a finite number of substituents (39 substituents in the '039 patent as compared to 23 in *Novartis* and 14 in *Driscoll*) in the formula provided in the specification. *Novartis*, No. PGR2018-00069, Paper 16 at 16; *Driscoll*, 562 F.2d at 1249-50. Thus, under precedents most relevant for the claims at issue here, the priority applications provide sufficient guidance to lead a person of ordinary skill in the art to the claimed subgenus.

The decisions on which Defendants rely do not dictate otherwise. (Mot. at 18-19, discussing *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1570 (Fed. Cir. 1996) and *In re Ruschig*, 379 F.2d 990, 995 (C.C.P.A. 1967).) *Fujikawa* addressed an effort to substitute one functional group in a claimed chemical formula for another—a concern not present here. *Novartis*, No. PGR2018-00069, Paper 16 at 14 (citing *Fujikawa*, 93 F.3d at 1570-71 (noting "it was not clear error to hold that substitution of isopropyl for cyclopropyl in a chemical formula was not supported in the disclosure")). Moreover, the *Fujikawa* opinion was anchored in the Federal Circuit's standard of review for the reversal of Board opinions, not any endorsement of the Board's reasoning itself. *Fujikawa*, 93 F.3d at 1571 ("While Fujikawa's arguments are not without merit, we cannot say, on this record, that the Board's decision was clearly erroneous."). *Ruschig* was not about supporting a claimed genus. Rather, the claim at issue in *Ruschig* was directed to a *single compound*, not a genus encompassing multiple compounds. *Ruschig*, 379 F.2d at 994 ("Specific claims to single compounds require reasonably specific supporting disclosure.").

One of Defendants' cited cases in fact supports Seagen. (Mot. at 13 (citing *Idenix Pharms. LLC v. Gilead Scis. Inc.*, 941 F.3d 1149 (Fed. Cir. 2019).) In *Idenix*, while the Federal Circuit ultimately held that the claims at issue were invalid for failing to meet the written description requirement, it explained that the patent at issue there "provides adequate written description *for the compounds within its formulas.*" *Idenix*, 941 F.3d at 1164 (emphasis added). Thus, the Federal Circuit signaled that the specification would have provided adequate written description for claims to compounds within the formulas disclosed in the specification. Likewise, the priority applications here provide adequate written description for the '039 patent claims, because the claimed compounds are within the disclosed formulas, which explicitly

enumerate a tetrapeptide and glycine and phenylalanine as express options (written in terms of a formula with optional functional groups) within the tetrapeptide.

B. There Are Genuine Issues of Material Fact in Dispute Regarding Whether the Priority Applications Provide Blaze Marks Guiding a Person of Ordinary Skill to the Claimed Tetrapeptide

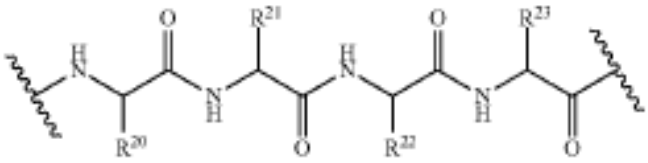
Defendants also argue that the priority applications are deficient because they lack "blaze marks" leading a person of ordinary skill in the art to the claimed tetrapeptides. (Mot. at. 20-27.) Again, whether the disclosure of the priority applications provided sufficient "blaze marks" from the viewpoint of a person of ordinary skill is disputed. Dr. Bertozzi offers her detailed analysis supporting her opinion that a person of ordinary skill would have understood that the specification of the '340 priority application guides the choice of tetrapeptides to those that only have glycine or phenylalanine. (Bertozzi ¶¶ 301-305.) DSC expert Dr. Lambert, on the other hand, opines that the priority applications do not describe ADCs with gly/phe-only tetrapeptides and lack any "blaze marks" to the claimed tetrapeptides. (Opp. Ex. 15, Lambert Opening Rep. at ¶¶ 342-344, 346-362.) This disagreement between the experts defeats summary judgment. *Allure Energy*, 2015 WL 11110607, at *2. Defendants have therefore failed to meet their burden to show that the priority applications do not meet the written description requirement under their "blaze marks" theory as well.

1. The Priority Applications Guide a Person of Ordinary Skill Toward the Claimed Tetrapeptides

As discussed above, the priority applications disclose different amino acids that could be used in sequences of different lengths, including tetrapeptides. Contrary to Defendants' assertions, the priority applications also provide guidance that would have guided a person of ordinary skill to select gly/phe tetrapeptides for potential use in an ADC development program. (Bertozzi ¶¶ 172, 302-303.)

The priority applications make repeated references to tetrapeptides and provide several examples, including the two shown below:

(IX)



wherein R^{20}, R^{21}, R^{22} and R^{23} are as follows:

R^{20}	R^{21}	R^{22}	R^{23}
H	benzyl	isobutyl	H; and
methyl	isobutyl	methyl	isobutyl.

(Bertozzi ¶¶ 172, 302-303; '340 application at ¶¶ 0690–91.) In the table, the first row indicates the four amino acids for use in the first exemplary tetrapeptide, indicating H for glycine (G), benzyl for phenylalanine (F), isobutyl for leucine (L) and H for glycine (G). The second row indicates the four amino acids for use in the second exemplary tetrapeptide, indicating methyl for alanine (A), isobutyl for leucine (L), methyl for alanine (A), and isobutyl for leucine (L). These two sequences, GFLG (glycine-phenylalanine-leucine-glycine) and ALAL (alanine-leucine-alanine-leucine), had been described in the literature. Although the utility of these sequences in ADCs had been questioned by some in the prior art, work by Seagen inventors that led to the '039 patent demonstrated that this prior concern was misplaced. (Bertozzi ¶¶ 173, 69-70, 77.) The priority applications also list a third tetrapeptide, GSVQ (glycine-serine-valine-glutamine). (Bertozzi ¶¶ 173, 302-303; '340 application at ¶ 697.) These examples, along with other exemplary amino acid sequences, would have guided a person of ordinary skill to gly/phe tetrapeptides. (Bertozzi ¶ 174.)

As Dr. Bertozzi explains, a person of ordinary skill looking to make ADCs with tetrapeptide linkers would have started with the tetrapeptide sequence examples in the priority applications, and in particular with the GFLG sequence due to the extensive publication history on that sequence. (*Id.*) In examining that sequence, a person of ordinary skill would have been drawn to consider several modifications based on the disclosure of the priority applications and the literature on substrates for lysosomal proteases. (*Id.*)

Persons of ordinary skill would have started their analysis at the C-terminus amino acid of the tetrapeptide because proteolytic cleavage by cathepsins typically occurs at the C-terminus. (Bertozzi ¶ 174.) In the GFLG example, the C-terminus amino acid is the last one in the sequence, referred to as position P1. (*Id.*) The priority applications refer to this position with the R^{23} functional group. (*Id.*) In the example, R^{23} is hydrogen, which means the amino acid is glycine. (*Id.*) The positions increment backward from there. Leucine (L) is in the P2 position. (*Id.*) Phenylalanine (F) is in the P3 position and so forth. (*Id.*) The person of ordinary skill would consider glycine to be a perfectly suitable amino acid at P1, as it would be unlikely to interfere with proteolytic cleavage through steric hindrance (glycine is the least sterically hindered amino acid because it does not have a side chain like other amino acids). (*Id.*) The other disclosed examples, with leucine or glutamine in P1, would not be as optimal. (*Id.*) At the P2 position, the priority applications' tetrapeptide examples disclose leucine, alanine, or valine. (*Id.*; '340 application at ¶¶ 691, 697.)

A person of ordinary skill would have considered substituting a phenylalanine at this position for multiple reasons. First, literature on cathepsin activity suggests that it processes substrates with phenylalanine at the P2 position more efficiently than other residues. (*Id.*) Second, phenylalanine is used at this position in peptides used in assays for cathepsin B. (*Id.*)

Third, the tripeptide examples provided in the priority applications all use phenylalanine in the P2 position, suggesting it could also be used in that location in a tetrapeptide sequence. (*Id.*; '340 application at ¶ 689.) Phenylalanine is also hydrophobic, and as discussed below, the literature suggests using a hydrophobic residue at this position. (*Id.*) For the P3 position, the tetrapeptide examples in the priority applications use phenylalanine, leucine, or serine. (Bertozzi ¶ 175; '340 application at ¶¶ 691, 697.) The priority applications also disclose that in a tripeptide, this position can be occupied by glycine or valine. (Bertozzi ¶ 175; '340 application at ¶ 689.) A person of ordinary skill could consider using glycine if they wished to have a less hydrophobic linker (as glycine is less hydrophobic than phenylalanine). (Bertozzi ¶ 175.) At the P4 position, the priority applications' tetrapeptide examples use glycine or alanine, and a person of ordinary skill would have known that either could be used in the tetrapeptide linker. (Bertozzi ¶ 176; '340 application at ¶¶ 691, 697.)

Therefore, a person of ordinary skill would have been able to take the exemplary peptides shown in the priority applications and arrive at tetrapeptides with glycine or phenylalanine at each position.

2. The Prior Art Disclosed Tetrapeptide Sequences with Gly/Phe

The art related to enzymatically degradable linkers reported different tetrapeptide sequences. (Bertozzi ¶ 182.) While these publications are not about ADCs, they would have informed persons of ordinary skill in the art how to design an ADC when read in the context of the disclosures of the '039 patent. (*Id.*)

Although some of the literature discounted the use of tetrapeptide sequences as protease cleavable linkers for ADCs, the disclosure of the priority applications guides the skilled person to reconsider this art for ADCs by including exemplary tetrapeptide sequences made of glycine and phenylalanine as suitable protease cleavable linkers for ADCs. (Bertozzi ¶¶ 69-70, 77, 182;

Opp. Ex. 16, SGIEDTX00000001 at -036.) As the inventors testified, an important aspect of the invention was discovering that the proteases are able to cleave a wide variety of peptide sequences, leading to the disclosure of different options for use in the amino acid unit, including glycine and phenylalanine. (Opp. Ex. 6, Kline Tr. [redacted] Opp. Ex. 7, Doronina Tr. at [redacted]; Bertozzi ¶ 179.) With the direction in the '039 patent to consider the activity of a broader array of proteases, and its reference to Gly-Phe-Leu-Gly (a sequence that had been written about extensively outside the context of ADCs), a person of ordinary skill in the art would have reevaluated non-ADC literature on tetrapeptides that are structurally similar.

For example, Nogusa 1997 discusses a tetrapeptide sequence with Gly-Gly-Gly-Gly for use in a non-ADC prodrug. (Bertozzi ¶ 182; Opp. Ex. 17, SGIEDTX00362135 ("Nogusa 1997").) The authors found that drug release was further improved when Phe was substituted for one of the Gly residues. (*Id.*) Nogusa 1997 states that prodrug conjugates with Gly-Gly-Phe-Gly and Gly-Phe-Gly-Gly sequences "show more potent in vivo antitumor effect" than the conjugates with previously reported tetrapeptide sequences in the literature. (*Id.*) Below are a few exemplary sequences that were reported in the literature that a person of ordinary skill would have guided toward based on the disclosures of the priority applications:

Tetrapeptide Sequence	Conjugates	Citation
Gly-Gly-Gly-Phe	DOTA with monoclonal antibody Lym-1 via GGGF tetrapeptide	Meares F., et al., Synthesis, metal chelate stability studies, and enzyme digestion of a peptide-linked DOTA derivative and its corresponding radiolabeled immunoconjugates, *Bioconjug Chem.* 1993;4(4):275-83. (Opp. Ex. 18, SGIEDTX00362109.)
Gly-Gly-Phe-Gly	Doxorubicin (DXR) with carboxymethylpullulan	Nogusa, H., et al., Antitumor effects and toxicities of carboxymethylpullulan-peptide-

	(CMPul) via GGFG tetrapeptide	doxorubicin conjugates, *Biol Pharm Bull.* 1997, 20(10):1061-5("Nogusa 1997"). (Opp. Ex. 17.)
Gly-Phe-Gly-Gly	Doxorubicin (DXR) with carboxymethylpullulan (CMPul) via GFGG tetrapeptide	Nogusa, H., et al., Antitumor effects and toxicities of carboxymethylpullulan-peptide-doxorubicin conjugates, *Biol Pharm Bull.* 1997;20(10):1061-5. (*Id.*)
Gly-Gly-Gly-Gly	Doxorubicin (DXR) with carboxymethylpullulan (CMPul) via GGGG tetrapeptide	Nogusa, H., et al., Antitumor effects and toxicities of carboxymethylpullulan-peptide-doxorubicin conjugates, *Biol Pharm Bull.* 1997, 20(10):1061-5. (*Id.*)
Gly-Leu-Phe-Gly	Doxorubicin (DXR) with carboxymethylpullulan (CMPul) via GLFG tetrapeptide	Nogusa, H., et al., Structure—Activity Relationships of Carboxymethylpullulan-Peptide-Doxorubicin Conjugates—Systematic Modification of Peptide Spacers, *Bioorganic & Medicinal Chemistry Letters* 10 (2000) 227-230 (Opp. Ex. 19, DSC_ENHERTU_00391669).

(Bertozzi ¶ 182.) Thus, prior art related to enzymatically degradable linkers would have informed the person of ordinary skill how to design an ADC when read in the context of the disclosures of the priority applications. (*Id.*)

3. Reliance on Prior Art in a Written Description Analysis Is Not Improper

Contrary to Defendants' argument, looking to guidance in the prior art is not improper in a written description context, and does not indicate that Seagen is relying on impermissible hindsight. (Mot. at 24.) This approach in fact heeds "a central tenet of . . . written description jurisprudence—that the disclosure must be read from the perspective of a person of skill in the art." *Novartis Pharms. Corp. v. Accord Healthcare, Inc.*, No. 2021-1070, 2022 U.S. App. LEXIS 58, at *22 (Fed. Cir. Jan. 3, 2022).

As the Federal Circuit recently reiterated in *Novartis Pharms.*, "context and the knowledge of those skilled in the art matter" in a written description analysis. *Id.* And "when

assessing what the written description reveals to a skilled artisan, common sense also matters." *Id.* This is why the specification's failure to mention a limitation that later appears in the claims "is not a fatal one when one skilled in the art would recognize upon reading the specification that the new language reflects what the specification shows has been invented." *All Dental Prodx, LLC v. Advantage Dental Prods., Inc.*, 309 F.3d 774, 779 (Fed. Cir. 2002). "Because the specification is viewed from the perspective of one of skill, in some instances, a patentee may rely on information that is well-known in the art for purposes of meeting the written description requirement. *Boston Sci.*, 647 F.3d at 1366; *Falkner v. Inglis*, 448 F.3d 1357, 1366 (Fed. Cir. 2006) (upholding validity of patent on basis of written description where patentee's expert testified that "'the skilled person would have been readily able to choose an essential vaccinia gene' based on references that have been publicly available"); *see also Immunex Corp. v. Sandoz Inc.*, 964 F.3d 1049, 1064 (Fed. Cir. 2020), *cert. denied*, 141 S. Ct. 2623 (2021) (rejecting defendant's argument that district court had "erred by looking outside the four corners of the specification or engaged in an 'obviousness-based' written description analysis" by crediting expert testimony that a person of ordinary skill would have been guided by the disclosures of two prior art references to arrive at the claimed invention). Of course, here, the limitations are explicitly set forth in the specification, in the formula for the peptide component of the linker.

Thus, nothing about Seagen's analysis relying on references available before the filing date of the priority applications is improper.

C. Defendants' Additional Arguments Are Unpersuasive

1. Actual Reduction to Practice of the Claimed Tetrapeptides Is Legally Irrelevant

Defendants point to testimony in which Seagen's inventors purportedly testified that they were not "in possession" of the claimed invention in 2003-2004. (Mot. at 7-8.) For example,

they point to testimony from Dr. Kline that "she was able to identify only one tetrapeptide linker that she made before 2005," and that it was a non-Gly/Phy-only tetrapeptide, and testimony from Dr. Doronina stating that she had "never made" an ADC containing a glycine phenylalanine tetrapeptide linker. (*Id.*)

None of this testimony is legally relevant to the issue of whether the priority applications provide adequate written description for the asserted claims. Rather, the inquiry is an objective one based on the specification itself, viewed from the viewpoint of a person of ordinary skill in the art. It is not based on actual reduction to practice of the claimed invention by the inventors. *Immunex Corp.*, 964 F.3d at 1064 ("actual reduction to practice is not required to show possession"); *Streck, Inc. v. Rsch. & Diagnostic Sys., Inc.*, 665 F.3d 1269, 1286–87 (Fed. Cir. 2012) (same). "The written description requirement requires possession as shown in the specification, *not as shown by prior experimental work*." *Allergan, Inc.*, 796 F.3d at 1309 (emphasis added). Rather, the written description requirement is met when the disclosure "allow[s] one skilled in the art to visualize or recognize the identity of the subject matter purportedly described." *Enzo Biochem, Inc. v. Gen–Probe Inc.*, 323 F.3d 956, 968 (Fed. Cir. 2002). There is no rigid requirement that the disclosure contain "either examples or an actual reduction to practice." *Ariad*, 598 F.3d at 1352. Accordingly, Defendants' reliance on the inventors' testimony regarding actual reduction to practice of the claimed tetrapeptides is misplaced.

2. The Inventors' Alleged Inability to Identify "Blaze Marks" Is Not Dispositive, and Is Mischaracterized by Defendants

Defendants also point to deposition testimony in which the Seagen inventors supposedly "admit that the Priority Applications do not have blaze marks directing to the claimed subgenus." (Mot. at 27.) The testimony is not an "admission" of lack of written description, and Defendants

mischaracterize what was said.

As an initial matter, the testimony at issue involves a highly objectionable, legalese-laced question, *i.e.*, whether the inventor "would agree with me that there are no blaze marks in that forest to identify the particular subgenus of 81 tetrapeptides that are recited in your claim," to which Seagen's counsel timely objected. (Mot. at 27 (citing MSJ Ex. 5, Senter Tr. at 458:17-22).) Even putting aside the objectionable nature of the questioning, an inventor's inability to identify particular disclosure in a specification does not establish lack of possession of the subject matter. *GEODynamics, Inc. v. Dynaenergetics US*, Inc., No. 2:17-CV-00371-RSP, 2018 WL 4680516, at *5 (E.D. Tex. Sept. 27, 2018) (Judge Roy Payne). In *GEODynamics*, when asked whether he could identify a portion of the patent that described a particular claim limitation, the inventor testified "I don't think those words are in the patent." *Id.* The court rejected defendants' argument that the inventor's testimony was an admission that the patent at issue did not disclose the claimed subject matter. *Id.* Instead, the court found that "by saying 'I don't think those words are in the patent,'" the inventor was merely stating that the patent "is silent as to that precise language. No rigid requirement exists that the disclosure contain specific examples to satisfy the written description requirement." (*Id.*) (emphasis added).

Defendants mischaracterize the inventors' testimony, in any event. Defendants contend that Seagen's named inventors provided "repeated, sworn admissions" that "Seagen had not even conceived of gly/phe-only tetrapeptide linkers as of 2003-2004, let alone described them in the priority applications." (Mot. at 14, 27.) That is inaccurate. Dr. Svetlana Doronina, a named inventor and drafter of the "The Amino Acid Unit" section of the priority applications that led to the '039 patent, testified otherwise. (Opp. Ex. 7, Doronina Tr. at [redacted].) She confirmed that [redacted]

[redacted].) Despite the questioning attorney's repeated attempts to dissuade Dr. Doronina, she affirmed [redacted] (Opp. Ex. 7, Doronina Tr. at [redacted]; Bertozzi ¶¶ 183, 316.)

Defendants also point to part of a sentence in a deposition transcript to contend that Dr. Doronina "testified that the specification provided just a 'research plan.'" (Mot. at 29 (citing MSJ Ex. 11, Doronina Tr. [redacted].) The complete sentence of Dr. Doronina's response makes clear that [redacted] (Opp. Ex. 7, Doronina Tr. at [redacted] With respect to the specification of the '039 patent, Dr. Doronina testified [redacted] (*Id.* at [redacted].)

Defendants' characterization of Dr. Senter's testimony is similarly flawed. Contrary to Defendants' assertion, Dr. Senter did not provide "a simple, case dispositive answer: 'It's true'" to a question about "blaze marks" in the '039 patent. (Mot. at 27 (citing MSJ Ex. 5, Senter Tr. 458:17-22).) First, Dr. Senter noted that [redacted]. (Opp. Ex. 20, Senter Tr. at [redacted]) Second, Defendants leave out key portions of Dr. Senter's complete response to this question. Viewed in its entirety, Dr. Senter's response makes clear that he

viewed the specification to provide sufficient disclosure that includes the particular subgenus that are cited in the claims:

[redacted]

(*Id*. at 458:17-459:4 (uncorrected);[1] Bertozzi ¶ 181.) Dr. Senter went on to explain the rationale behind his understanding, which was based on [redacted]

(Opp. Ex. 20, Senter Tr. at [redacted] Dr. Senter also testified that [redacted] (*Id*. at [redacted]; Bertozzi ¶ 181.)

Defendants cannot cherry-pick portions of Dr. Senter's testimony and ignore the context to arrive at a contrary conclusion. Far from a "demonstratively false errata" as Defendants argue (Mot. at fn. 20), the errata is entirely consistent with and reflects his testimony.[2] Even if there

[1] As discussed below, Dr. Senter submitted an errata to clarify this testimony, but because Defendants rely on the uncorrected form, Seagen provides the uncorrected quote here in its entirety for context.

[2] Defendants argue that Dr. Senter's clarification results in an "illogical response," but as discussed above, Dr. Senter's clarification is fully consistent with his deposition testimony as a whole. (Opp. Ex. 20, Senter Tr. at 458:22–459:4 (corrected) ("It's true that we have a broad disclosure.") The only binding authority cited by Defendants, *Gonzalez v. Fresenius Medical Care North America*, is inapposite. There, the deponent submitted an errata that was "literally word[ed]" by her attorney in contradiction to the deponent's original testimony to better support the allegations in the complaint. *Gonzalez*, 689 F.3d 470, 480 (5th Cir. 2012). Dr. Senter's errata is not contradictory to his original testimony. Defendants' other cited authorities—neither

were a discrepancy in Dr. Senter's testimony, any evaluation of his testimony should be left to the jury. *See Huawei Techs. Co. v. T-Mobile US, Inc.*, No. 2:16-CV-00055-JRG-RSP, 2017 WL 5165606, at *7 (E.D. Tex. Oct. 15, 2017), *report and recommendation adopted sub nom. Huawei Techs. Co. v. T-Mobile US, Inc.*, No. 2:16-CV-00055-JRG-RSP, 2017 WL 5157687 (E.D. Tex. Nov. 7, 2017) ("In light of the witness's original testimony, and subsequent change to that testimony, the Court must be cautious not to make a determination about the credibility of the witness at the summary judgment stage.").

The testimony of the other co-inventors, Drs. Toki and Kline, does not support Defendants' assertions either. In response to a question about what disclosure in the patent directs a scientist to gly/phe-only tetrapeptides, Dr. Toki pointed to [redacted] (Opp. Ex. 8, Toki Tr. at [redacted]; Bertozzi ¶ 311.) In response to a similar question, Dr. Kline testified that [redacted] (Ex. 15, Kline Tr. at [redacted], Opp. Ex. 6, [redacted]; Bertozzi ¶ 310.) Even when answering a question using legally-loaded terminology such as "blaze marks," Dr. Kline testified that [redacted] (Ex. 15, Kline Tr. at [redacted]; Bertozzi ¶ 310.) She continued to explain that a person of ordinary skill would [redacted]

[redacted] which is binding on this Court—affirmatively permit the submission of clarifying amendments that "reflect the deponent's original testimony." *Devon Energy Corp. v. Westacott*, C.A. No. H-09-1689, 2011 WL 1157334, at *6 (S.D. Tex. Mar. 24, 2011); *see also Burns v. Bd. of Cnty. Comm'rs of Jackson Cnty.*, 330 F.3d 1275, 1282 (10th Cir. 2003) ("Factors to be considered in determining whether an affidavit presents a sham issue include […] 'whether the earlier testimony reflects confusion which the affidavit attempts to explain.'").

[redacted] (Ex. 15, Kline Tr. at [redacted]) Not only does her testimony make clear that the '039 patent teaches the specific tetrapeptides with glycine and phenylalanine, it also provides meaningful disclosure as to how to make such tetrapeptides. She further testified that [redacted] (Opp. Ex. 6, Kline Tr. at [redacted]; Bertozzi ¶¶ 75–77 *citing* [redacted].)

Accordingly, the inventors' testimony does not demonstrate that they were not "in possession" of the claimed invention as of 2003/2004. If anything, it demonstrates the existence of even more disputed issues of material fact, precluding summary judgment.

3. The Blaze Marks Need Not Point Toward the Exact Claimed Subgenus

Defendants also argue that the subgenera identified by Dr. Bertozzi are not relevant, as "[c]rucially for purposes of" their motion is that the blaze marks identified by Seagen allegedly point to the "wrong subgenus." (Mot. at 25.) According to Defendants, because Seagen's expert, Dr. Bertozzi, identified two subgenera that included tetrapeptides within the claimed genus but were not limited to the exact 81 claimed tetrapeptides, any blaze marks pointing toward the genera "necessarily fails . . . as a matter of law." (*Id.* at 27.)

Yet neither of the cases Defendants cite supports this novel theory. (*Id.* at 27 (citing *Fujikawa*, 93 F.3d at 1571; *Boston Sci.*, 647 F.3d at 1367. *Fujikawa* merely states that the "application contained no blazemarks as to what compounds, other than those disclosed as preferred, might be of special interest." 93 F.3d at 1571. It does not stand for the proposition that the blaze marks must point to the exact claimed subgenus, no more and no less. Similarly, in *Boston Scientific*, far from requiring the specification to point to the exact claimed subgenus

(macrocyclic triene analogs), the CAFC faulted the specification for failing to disclose even a "*single species of* 'macrocyclic triene analogs' or a *single species of* any analog of rapamycin." 647 F.3d at 1369 (emphasis added).

Other cases cited by Defendants similarly rely on blaze marks guiding a person of ordinary skill toward one or more species within the claimed genus, rather than toward the exact subgenus. In *Novozymes A/S v. DuPont Nutrition Biosciences APS*, 723 F.3d 1336, 1349 (2013), the CAFC found no blaze marks for the claimed genus because "one searches the 2000 application in vain for the disclosure of *even a single species that falls within the claims* or for any 'blaze marks' that would lead an ordinarily skilled investigator toward such a species among a slew of competing possibilities." And *Novartis* summed up the standard most clearly, stating that "where the specification describes a broad genus and the claims are directed to a single species or a narrow subgenus, we have held that the specification must contain 'blaze marks' that would lead an ordinarily skilled investigator *toward such a species* among a slew of competing possibilities." *Novartis Pharms.*, 2022 U.S. App. LEXIS 58, at *5 (emphasis added).

Accordingly, Defendants' overly restrictive interpretation of case law pertaining to blaze marks should be rejected as unsupported by precedent.

4. Defendants' Commentary on Seagen's Prosecution Strategy Is Wholly Irrelevant to Written Description

Throughout their motion, Defendants make irrelevant references to Seagen's patent prosecution strategy, implying that Seagen engaged in inappropriate conduct during prosecution. Nothing about Seagen's prosecution strategy was improper in any way. Nor does it have any bearing on the legal issues relevant to this motion.

Defendants refer to Seagen's supposedly "predatory behavior" to "claim[] the invention of others" by claiming the gly/phe tetrapeptides after the launch of Defendants' commercial

product. (Mot. at 1, 8, 10-11.) But as the Federal Circuit has repeatedly recognized, "there is nothing improper, illegal or inequitable in filing a patent application for the purpose of obtaining a right to exclude a known competitor's product from the market; nor is it in any manner improper to amend or insert claims intended to cover a competitor's product the applicant's attorney has learned about during the prosecution of a patent application." *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 874 (Fed. Cir. 1988); *see also Texas Instruments Inc. v. U.S. Int'l Trade Comm'n*, 871 F.2d 1054, 1065 (Fed. Cir. 1989); *Ricoh Co. v. Nashua Corp.*, 185 F.3d 884 (Table), No. 97-1344, 1999 WL 88969, at *2 (Fed. Cir. Feb. 18, 1999) (unpublished). Defendants' commentary on Seagen's prosecution strategy therefore has no legal relevance.

VI. CONCLUSION

The substantial genuine issues of material fact in dispute and Defendants' misinterpretation of the applicable law preclude the grant of summary judgment. Defendants' motion for summary judgment of invalidity should be denied.

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By: */s/ Michael A. Jacobs*

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that counsel of record who are deemed to have consented to electronic services are being served with a copy of this document via the Court's CM/ECF system per Local Rule CV-5(a)(3) on this the 20th day of January, 2022.

/s/ *Melissa R. Smith*

CERTIFICATE OF AUTHORIZATION TO FILE UNDER SEAL

I hereby certify that the foregoing document is authorized to be filed under seal pursuant to the Protective Order entered in this case.

/s/ *Melissa R. Smith*